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01/29/2008 DSMALLS #00000002 230785 10815320  
01 FC:1251 120.00 CR

1251

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: H. Binz et al. )  
Title: CARRIER PROTEIN HAVING AN )  
ADJUVANT EFFECT, IMMUNOGENIC )  
COMPLEX CONTAINING IT, )  
PROCESS FOR THEIR PREPARATION, )  
NUCLEOTIDE SEQUENCE AND )  
VACCINE )  
Serial No. 10/815,320 ) Group Art Unit: 1645  
Filed: April 1, 2004 ) Examiner: S. Devi

**REFUND REQUEST LETTER**


Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

As per the attached Notice from the USPTO dated December 14, 2007 (Exhibit A), please issue a refund in the amount of \$120.00 which was paid by Deposit Account No. 23-0785 on January 29, 2008 (Exhibit B), for filing of a Response to Office Action dated September 24, 2007 which was timely filed on December 26, 2007 (Exhibit C). Should you have any further questions, please don't hesitate to contact the undersigned.

Respectfully submitted,

Date: February 19, 2008

  
Mark V. Polyakov, Reg. No. 54,377  
Wood, Phillips, Katz, Clark & Mortimer  
500 West Madison Street, Suite 3800  
Chicago, Illinois 60661-4592  
Telephone: (312) 876-1800  
Facsimile: (312) 876-2020

**Closing of the United States Patent and Trademark Office  
on Monday, December 24, 2007**

The United States Patent and Trademark Office (USPTO) will be closed on Monday, December 24, 2007. Since Tuesday, December 25, 2007 is a Federal holiday, the USPTO will consider both Monday, December 24, 2007 and Tuesday, December 25, 2007, to be a "Federal holiday within the District of Columbia" under 35 U.S.C. § 21(b) and 37 C.F.R. §§ 1.6, 1.7, 1.9, 2.2(d), 2.195 and 2.196. Any action or fee due on these days (or the preceding Saturday (December 22, 2007) or Sunday (December 23, 2007)) will be considered as timely for the purposes of, e.g., 15 U.S.C. §§ 1051(b), 1058, 1059, 1062(b), 1063, 1064, 1126(d), or 35 U.S.C. §§ 119, 120, 133 and 151, if the action is taken, or the fee paid, on the next succeeding business day on which the USPTO is open, that is, Wednesday, December 26, 2007. 37 C.F.R. §§ 1.7(a) and 2.196.

37 C.F.R. §§ 1.6(a)(2), 2.195(a)(4) and 2.198 provide that correspondence deposited in the Express Mail Service of the United States Postal Service (USPS) in accordance with 37 C.F.R. §§ 1.10 or 2.198 will be considered filed on the date of deposit (as shown by the "date-in" on the Express Mail mailing label) with the USPS. Thus, any paper or fee properly deposited in the Express Mail Service of the USPS on Monday, December 24, 2007, or Tuesday, December 25, 2007, in accordance with 37 C.F.R. §§ 1.10 or 2.198 will be considered filed on its respective date of deposit in the Express Mail Service of the USPS (as shown by a "date-in" of December 24, 2007, or December 25, 2007, on the Express Mail mailing label, respectively).

37 C.F.R. § 1.6(a)(4) and 37 C.F.R. § 2.195(a)(2) provide that patent and trademark-related correspondence transmitted electronically to the USPTO will be considered filed in the USPTO on the date the USPTO received the electronic transmission. Thus, any patent and/or trademark-related correspondence transmitted electronically to the USPTO on Monday, December 24, 2007, or Tuesday, December 25, 2007, will be considered filed in the USPTO on the date the USPTO received the complete electronic transmission. Correspondence successfully received by the USPTO through the patent Electronic Filing System (EFS-Web) will receive the date as indicated on the Acknowledgment Receipt.

12/14/07  
DATE

  
JON W. DUDAS  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office

Exhibit A



# United States Patent and Trademark Office



## Deposit Account Statement

Requested Statement Month: January 2008  
 Deposit Account Number: 230785  
 Name: WOOD, PHILLIPS, KATZ, CLARK & MORTIMER  
 Attention: DONNA GVOZDEN  
 Street Address 1: 500 WEST MADISON STREET  
 Street Address 2: SUITE 3800  
 City: CHICAGO  
 State: IL  
 Zip: 60661  
 Country: UNITED STATES

DATE	SEQ	POSTING REF TXT	ATTORNEY DOCKET NBR	FEE CODE	AMT	BAL
01/02	7	PCT/US07/26455	10468P00010PC	1602	\$955.00	\$1,104.00
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01/11	25	60690545	COR1896P0100US	1807	\$50.00 ✓	\$7,047.00
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01/16	9905	60936395	VAL06131P01001CL	8007	\$20.00 ✓	\$6,632.00

Exhibit B

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01/16 10276 60898458

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01/23 9321 6328031

01/23 7 11024183

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01/23 12465 6062435

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01/23 12921 6578572

01/23 12922 6328031

01/24 2 PCT/US07/23897

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01/28 3065 0201400238

01/28 9409 60690545

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01/28 222 10962348

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COR01896P00111 &amp; 121AR

01896P00100US

1229 10183P00060US

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00467P01111

PIE1514P01821US

1231 00917P00470US

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8007 \$20.00 \$6,812.00

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8007 \$20.00 \$2,612.00

8014 \$375.00 \$2,237.00

START  
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CHARGES  
\$9,984.00SUM OF  
REPLENISH  
BALANCE  
\$10,162.00 \$2,237.00Exhibit \*  
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on entry

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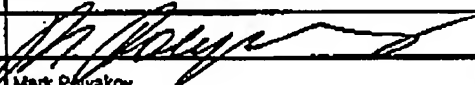
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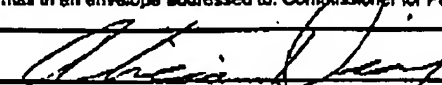
Approved for use through 10/31/2007, OMB 0851-0031  
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number.

<b>TRANSMITTAL FORM</b>  <small>(to be used for all correspondence after initial filing)</small>	Application Number	10315,320	
	Filing Date	April 1, 2004	
	First Named Inventor	Hans Binz et al.	
	Art Unit	1645	
	Examiner Name	Devi, Sarvamangala J N	
Total Number of Pages in This Submission	10	Attorney Docket Number	PIE1514P0182US

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input checked="" type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement  <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Return receipt postcard
Remarks _____		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	Wood Phillips Katz Clark & Mortimer		
Signature			
Printed name	Mark Polyakov		
Date	December 28, 2007	Reg. No.	54,377

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:			
Signature			
Typed or printed name	Alicia Diaz	Date	December 28, 2007

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to be 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-0199 and select option 2.

Exhibit C

PIE01514P00182US

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

H. Binz et al.

Serial No. 10/815,320

Filed: 04/01/2004

) CARRIER PROTEIN HAVING AN  
) ADJUVANT EFFECT, IMMUNOGENIC  
) COMPLEX CONTAINING IT,  
) PROCESS FOR THEIR PREPARATION,  
) NUCLEOTIDE SEQUENCE AND  
) VACCINE

) Group Art Unit: 1645

) Examiner: S. Devi

**RESPONSE TO OFFICE ACTION**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the Office Action dated September 24, 2007 in connection with the above-identified patent application, please consider the following amendments and remarks. If any additional fees are required as a result of the filing of this paper, the Commissioner is hereby authorized to charge to Deposition Account No. 23-0785 any such fees.

**AMENDMENTS TO THE SPECIFICATION**

Amendments to the Specification begin on page 2 of this paper.

**AMENDMENTS TO THE CLAIMS**

Amendments to the claims are reflected in the listing of claims which begins on page 6 of this paper.

**REMARKS**

Remarks begin on page 9 of this paper.

Response to OA dated 09/24/2007  
10/815,320  
PIE01514P00182US

**In the Specification:**

Please insert the following paragraph at the top of the first page and immediately before "CROSS-REFERENCE TO RELATED APPLICATIONS":

**TITLE OF THE INVENTION**

**Carrier Protein Having an Adjuvant Effect**

Please replace the paragraph immediately after "CROSS-REFERENCE TO RELATED APPLICATIONS" with the following:

This application is a division of Application Serial No. 09/679,750, filed 10/05/2000, now US Patent No. 6,780,420, which is a continuation of application Serial No. 08/836,500, filed 08/11/97, now US Patent No. 6,197,929, which is a national stage 371 application of the international application PCT/FR95/01463, which claims foreign priority to application 94,13306 filed 07/11/1994 in France.

Please insert the following heading immediately after the paragraph dealing with "CROSS-REFERENCE TO RELATED APPLICATIONS":

**STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH AND DEVELOPMENT**

**Not Applicable**

Please insert the following heading immediately after the paragraph dealing with "STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH AND DEVELOPMENT":

**THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT**

**Not Applicable**

Please insert the following heading immediately after the paragraph dealing with "THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT":

**REFERENCE TO A "SEQUENCE LISTING"**



Response to OA dated 09/24/2007  
10/815,320  
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The application contains "Sequence Listing" in the computer readable form. The computer readable form is identical with that filed in Application Serial No. 08/836,500, filed 08/11/97, now US Patent No. 6,197,929.

Please insert the following heading immediately after the paragraph dealing with "Reference to a "Sequence Listing"":

#### FIELD OF THE INVENTION

Please insert the following heading immediately after line 9 of page 1 and immediately before line 10 (i.e. the sentence that starts, "The development of vaccines...") of page 1 in the originally submitted translation:

#### BACKGROUND ART

Please insert the following heading immediately after line 32 of page 1 and immediately before line 33 (i.e. the sentence that starts, "The Applicant has demonstrated...") of page 1 in the originally submitted translation:

#### SHORT SUMMARY OF THE INVENTION

Please insert the following heading immediately after line 11 of page 6 and immediately before line 12 (i.e. the sentence that starts, "In these examples...") of page 6 in the originally submitted translation:

#### BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Please insert the following heading immediately after line 24 of page 6 and immediately before line 25 (i.e. the sentence that starts, "Example 1: Isolation...") of page 6 in the originally submitted translation:

#### DETAILED DESCRIPTION OF THE INVENTION

Please replace the paragraph that starts on line 4 of page 7 with the following:

The pellets obtained after the second precipitation are resuspended in a 1% solution of zwittergent Zwittergent® 3-14.

Please replace the paragraph that starts on line 13, page 7 with the following:

The proteins of the MP fraction are dialysed against a 20 mM Tris/HCl, pH 8.0; 0.1% zwittergent Zwittergent® 3-14 buffer. The dialysate is loaded onto a column

Response to OA dated 09/24/2007  
10/815,320  
PIE01514P00182US

containing a support of the strong anion exchanger type (column of  $\phi = 50$  mm x  $H = 250$  mm, Biorad® Macrorep High Q gel) which is equilibrated in the above-described buffer. The P40 protein is eluted at an NaCl concentration of 50 mM in the equilibration buffer.

Please replace the paragraph that starts on line 21, page 7 with the following:

The fractions containing the P40 are pooled and dialysed against a 20 mM citrate, pH 3.0; 0.1% ~~zwittergent~~ Zwittergent® 3-14 buffer. The dialysate is loaded onto a column containing a support of the strong cation exchanger type (dimensions of the column:  $\phi = 25$  mm x  $H = 160$  mm, Biorad® Macrorep High S gel) which is equilibrated in the 20 mM citrate, pH 3.0; 0.1% ~~zwittergent~~ Zwittergent® 3-14 buffer. The P40 protein is eluted at an NaCl concentration of 0.7 M. The fractions containing the P40 are pooled and concentrated by ultrafiltration using a Minitan® Millipore tangential flow filtration system employing membrane discs having a cutoff threshold of 10 kDa.

Please replace the paragraph that starts on line 9, page 10 with the following:

#### Gene amplification

Lysis buffer: 25 mM Taps, pH 9.3  
2 mM MgCl<sub>2</sub>

Amplification  
buffer: 25 mM Taps, pH 9.3  
2 mM MgCl<sub>2</sub>  
0.1% Tween® 20  
200 mM dNTP.

Please replace the paragraph that starts on line 16, page 10 with the following:

TST (20x) :	Tris base	0.5 M
	HCl	0.3 M
	NaCl	4 M
	Tween® 20	1%
	EDTA	20 mM

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Washing buffer:	Tris HCl	50 mM	pH 8.5
	MgCl <sub>2</sub>	5 mM	

Denaturation solution:	Gua - HCl	7.8 M	pH 8.5
	Tris-HCl	28 mM	

Renaturation solution:	Gua-HCl	0.5 M	pH 8.5
	Tris-HCl	25 mM	
	NaCl	150 mM	
	Tween® 20	0.05%	

Please replace the paragraph that starts on line 24, page 11 with the following:

These reactions are carried out in 100 µl of amplification buffer using 5 pmol of each primer and 1 unit of Taq polymerase enzyme (Perkin Elmer Cetus). Each cycle comprises one denaturation step of 30 seconds at 95°C, followed by hybridization of the primer to the DNA and an extension of one minute at 72°C. 30 cycles are performed in this way using a Perkin Elmer Cetus "Gen Amp PCR"® 9000 thermocycler.

Please replace the paragraph that starts on line 2, page 12 with the following:

The fragments which have thus been cloned are sequenced on an Applied Biosystems 373 automated DNA Sequencer. The sequencing reactions are carried out using the "Dye Terminator"® kit in accordance with the supplier's (Applied Biosystems) recommendations either on double-stranded DNA obtained after gene amplification or derived from a maxiprep, or on single-stranded DNA derived from denatured PCR fragments (Hultman, T. et al., 1989, Nucleic Acids Rev. 17: 4937-4946).

Response to OA dated 09/24/2007  
10/815,320  
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**In the Claims:**

1. (Cancelled)
2. (Cancelled)
3. (Cancelled)
4. (Cancelled)
5. (Cancelled)
6. (Cancelled)
7. (Withdrawn) DNA sequence encoding an adjuvant comprising at least the fragment of the P40 protein *Klebsiella pneumoniae*, said fragment having the amino acid sequence of SEQ ID No: 8.
8. (Cancelled)
9. (Cancelled)
10. (Cancelled)
11. (Cancelled)
12. (Cancelled)
13. (Cancelled)
14. (Cancelled)
15. (Cancelled)
16. (Withdrawn) A pharmaceutical composition comprising said DNA sequence of claim 7, and a pharmaceutically acceptable carrier.
17. (Withdrawn) A vaccine for intramuscular or intradermal administration comprising said DNA sequence of claim 7.

Response to OA dated 09/24/2007  
10/815,320  
PIE01514P00182US

18. (Cancelled)
19. (Currently Amended) ~~A Process~~ process for increasing the immunogenicity of an antigen or a hapten, characterized in that the said process comprises the step of attaching the antigen or the hapten is attached to an adjuvant to form an immunogenic complex, said adjuvant comprising ~~the a fragment having the sequence 127 to 179~~ (SEQ ID No. 8) of the P40 protein of ~~Klebsiella K. pneumoniae pneumoniae~~ having the sequence SEQ ID No. 2.
20. (Currently Amended) ~~The Process~~ process according to claim 19, characterized in that said adjuvant is ~~the a fragment having the sequence 108 to 179~~ (SEQ ID No. 6) of the P40 protein of ~~K. pneumoniae having the sequence ID No. 2 Klebsiella pneumoniae~~.
21. (Currently Amended) ~~The Process~~ process according to claim 19, characterized in that said adjuvant is ~~the a fragment having the sequence 1 to 179~~ (SEQ ID No. 4) of the P40 protein of ~~K. pneumoniae having the sequence ID No. 2 Klebsiella pneumoniae~~.
22. (Currently Amended) ~~The Process~~ process according to claim 19, characterized in that said adjuvant is the P40 protein of ~~K. pneumoniae~~ Klebsiella pneumoniae having the sequence ID No. 2.
23. (Cancelled)
24. (Currently Amended) ~~The Process~~ process according to claim 19, characterized in that said antigen or ~~a the~~ hapten consists of ~~a an~~ immunogenic fragment of the G protein of the respiratory syncytial virus (RSV).
25. (Currently Amended) ~~The Process~~ process according to claim 19, characterized in that said antigen or ~~the a~~ hapten is attached to the adjuvant by a covalent bond.

Response to OA dated 09/24/2007  
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PIE01514P00182US

26. (Currently Amended) The Process process according to claim 19, characterized in that said antigen or the hapten is attached to the adjuvant by chemical coupling.
27. (Currently Amended) The Process process according to claim 19, characterized in that said antigen or the hapten is fused to the adjuvant by genetic manipulation.
28. (Currently Amended) The Process process according to claim 19, characterized in that said antigen or the a hapten which is attached to the adjuvant, is fused to a protein which is a receptor for a serum protein.
29. (Currently Amended) The Process process according to claim 19, characterized in that said antigen or the a hapten which is attached to the adjuvant, is fused to a protein which is a receptor for the human serum albumin.

Response to OA dated 09/24/2007  
10/815,320  
PIE01514P00182US

### REMARKS

This is in response to the Office Action mailed on September 24, 2007. Claims 19-29 are currently pending and are at issue.

According to the Examiner's suggestion, Applicants have amended the specification to introduce Section Headings and to correct other informalities.

Claim 24 has been further amended to recite "immunogenic" fragment of the G protein. Support can be found, for example, at page 5, lines 12-16.

#### §112, Second Paragraph

The Office Action rejected claims 19-29 under 35 U.S.C. §112, second paragraph as allegedly being indefinite. Applicants have amended claims 19-22 and 24-29 and have canceled claim 23. Applicants believe that the amendments address and overcome the rejection.

#### Conclusion

Applicants respectfully submit that all rejections have been overcome by amendments and/or arguments. Favorable consideration and allowance of claims is respectfully requested. If the Examiner has any questions or concerns, she is welcome to telephone the undersigned attorney.

Respectfully submitted,

  
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Response to OA dated 09/24/2007  
10/815,320  
PIE01514P00182US

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